

and Child Health) or title XX (Social Services) programs, such as penalties assessments and exclusions under sections 1128, 1128A or 1128B of the Act, the disclosing entity must also provide that information.

(b) *Time and manner of disclosure.* (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicare standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency will promptly furnish the information to the Secretary.

(2) Any disclosing entity that is not subject to periodic survey and certification must supply the information specified in paragraph (a) of this section to HCFA before entering into a contract or agreement with Medicare or before being issued or reissued a billing number as a part B supplier.

(3) A disclosing entity must furnish updated information to HCFA at intervals between recertification, or re-enrollment, or contract renewals, within 35 days of a written request. In the case of a part B supplier, the supplier must report also within 35 days, on its own initiative, any changes in the information it previously supplied.

(c) *Consequences of failure to disclose.*

(1) HCFA does not approve an agreement or contract with, or make a determination of eligibility for, or (in the case of a part B supplier) issue or re-issue a billing number to, any disclosing entity that fails to comply with paragraph (b) of this section.

(2) HCFA terminates any existing agreement or contract with, or withdraws a determination of eligibility for or (in the case of a part B supplier) revokes the billing number of, any disclosing entity that fails to comply with paragraph (b) of this section.

(d) *Public disclosure.* Information furnished to the Secretary under the provisions of this section shall be subject to public disclosure as specified in 20 CFR part 422.

[44 FR 41642, July 17, 1979, as amended at 57 FR 27306, June 18, 1992]

## Subpart D—Access to Books, Documents, and Records of Subcontractors

SOURCE: 47 FR 58267, Dec. 30, 1982, unless otherwise noted.

### § 420.300 Basis, purpose, and scope.

This subpart implements section 1861(v)(1)(I) of the Act, which requires, for Medicare payment under certain provider contracts, access by the Secretary, upon written request, and the Comptroller General, and their duly authorized representatives, to certain contracts for services and to books, documents, and records necessary to verify the costs of the services. The contracts affected are those between providers and their subcontractors, and between the subcontractors and organizations related to the subcontractor by control or common ownership. It also specifies the criteria by which HHS will determine whether to request access to books, documents, and records.

### § 420.301 Definitions.

For purposes of this subpart—

*Books, documents, and records* means all writings, recordings, transcriptions and tapes of any description necessary to verify the nature and extent of the costs of the services provided by the subcontractor.

*Common ownership* means that an individual or individuals possess significant ownership or equity in the subcontractor and the entity providing the services under the contract.

*Contract for services* means a contract through which a provider obtains the performance of an act or acts, as distinguished from supplies or equipment. It includes any contract for both goods and services to the extent the value or cost of the service component is \$10,000 or more within a 12-month period.

*Control* means that an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions of policies of an organization.

*Provider* means a hospital, skilled nursing facility, home health agency, hospice or comprehensive outpatient

rehabilitation facility, or a related organization (as defined in §413.17 of this chapter) of any of these providers.

*Related to the subcontractor* means that the subcontractor is, to a significant extent, associated or affiliated with, owns, or is owned by, or has control of or is controlled by, the organization furnishing the services, facilities, or supplies.

*Subcontractor* means any entity, including an individual or individuals, that contracts with a provider to supply a service, either to the provider or directly to a beneficiary, for which Medicare reimburses the provider the cost of the service. This includes organizations related to the subcontractor that have a contract with the subcontractor for which the cost or value is \$10,000 or more in a 12-month period.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984; 51 FR 34833, Sept. 30, 1986]

**§ 420.302 Requirement for access clause in contracts.**

(a) *Applicability.* This subpart applies to contracts—

(1) Between a provider and a subcontractor and, where subject to section 1861(v)(1)(I)(ii) of the Act, between a subcontractor and an organization related to the subcontractor;

(2) Entered into or renewed after December 5, 1980; and

(3) For services the cost or value of which is \$10,000 or more over a 12-month period, including contracts for both goods and services in which the service component is worth \$10,000 or more over a 12-month period.

(b) *Requirement.* Any contract meeting the conditions of paragraph (a) of this section must include a clause that allows the Comptroller General of the United States, HHS, and their duly authorized representatives access to the subcontractor's contract, books, documents, and records until the expiration of four years after the services are furnished under the contract or subcontract. The access must be provided for in accordance with the provisions of this subpart. The clause must also allow similar access by HHS, the Comptroller General, and their duly authorized representatives to contracts subject to section 1861(v)(1)(I)(ii) of the

Act between a subcontractor and organizations related to the subcontractor and to books, documents, and records.

(c) *Prohibition against Medicare reimbursement.* If a contract subject to the requirements of this subpart does not contain the clause required by paragraph (b) of this section, HCFA will not reimburse the provider for the cost of the services furnished under the contract and will recoup any payments previously made for services under the contract. However, in order to avoid nonreimbursement or recoupment, providers will have until July 30, 1983, to amend those contracts entered into or renewed after December 5, 1980, and before January 31, 1983, that do not conform to the requirements of paragraph (b) of this section.

[47 FR 58267, Dec. 30, 1982, as amended at 49 FR 13703, Apr. 6, 1984]

**§ 420.303 HHS criteria for requesting books, documents, and records.**

HHS will generally request books, documents, and records from a subcontractor only if one of the following situations exists and the question cannot satisfactorily and efficiently be resolved without access to the books, documents, and records:

(a) HHS has reason to believe that the costs claimed for services of the subcontractor are excessive or inappropriate.

(b) There is insufficient information to judge the appropriateness of the costs.

(c) There is a written accusation with suitable evidence against the provider or subcontractor of kickbacks, bribes, rebates, or other illegal activities.

(d) There is evidence of a possible nondisclosure of the existence of a related organization.

**§ 420.304 Procedures for obtaining access to books, documents, and records.**

(a) *Contents of the request.* Requests for access will be in writing and contain the following elements:

(1) Reasonable identification of the books, documents, and records to which access is being requested.

(2) Identification of the contract or subcontract in which costs are being